EXHIBIT B

DATE: May 21, 1992

FROM: Chief
Distribution Management Branch, OBA

SUBJECT: Freeze on all Medicare Claims at the Federal Records Centers

TO: Regional Office Records Liaison Officers

On May 6, the Department of Justice (DOJ) requested the Health Care Financing Administration freeze all Medicare claims and payment records because of current and future litigation (attached). DOJ projects it will be several years before these records can again be routinely destroyed.

In answer to our request (see May 12 letter attached), the Assistant Archivist stated they would continue to keep Medicare records currently stored in the records centers, but as a result of this freeze, they could not accept any additional Medicare records into the centers.

Since Medicare contractors do not have the ability to store these records onsite, an alternative storage location must be found. We will be meeting next week with the Assistant Archivist and the Department of Justice to resolve this issue. In the meantime, please notify all Medicare contractors they cannot transfer any additional records to the FRCs.

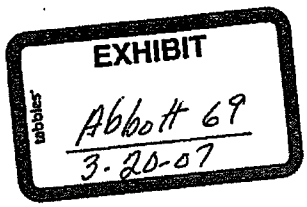
If you have any questions, please call me on FTS (410) 966-7892 or Vickie Robey, HCFA's Records Officer, on FTS (410) 966-7883.

Jane Eagan

Attachments

cc: Director, OFO
Director, BPO
bcc:Bill Zavoina
Don Posen
Les Horneman
Lee Mosedale

OBA/OAS/DPDS/DMB VRobey:var 5/19/92
DISC: 1992 RECORDS
TITLE: FRZE-RLO



September 30, 1997

NOTE TO: HCFA Regional Records Liaison Officers

SUBJECT: Department of Justice Ordered Freeze on Routine Destruction of HCFA Records - ACTION

This note modifies the prior instructions regarding the Department of Justice (DOJ) imposed records freeze and updates you on efforts we are taking to modify/rectify the records storage problems.

As you know, in May 1992, DOJ ordered HCFA to freeze the destruction of all Medicare claim, payment and administrative records. This order includes all Regional Office and contractor records such as EOMBs, benefit checks, remittance advices, cost reports and related documents, medical documentation, reopening actions, claims appeal cases at all levels of appeal (reconsideration, review, fair hearing, administrative law judge hearing, Appeals Council review, any subsequent court ordered action), all correspondence, etc.. Please note that the freeze applies to all formats of records (hard copy, microfilm, optical image, computer tapes/discs, etc.). In addition, please note that contractors must not only retain electronic records, including those inherited because of a workload consolidation or transition, but also must retain the ability to access, read and act upon the retained records. If a contractor has retained electronic records generated by one system, it must retain the ability to access, read and act upon the retained records even if a different system is currently being used.

As a result of the freeze, the Federal Records Centers (FRCs) could no longer accept any additional records for storage from Medicare contractors. On July 7, 1992, we authorized the contractors to procure offsite storage but only on a month-to-month basis if a storage problem resulted from the freeze. Some contractors have indicated that procuring storage on a month-to-month basis is more costly than other extended arrangements. We are now authorizing contractors to secure appropriate offsite storage through quarterly, semi-annual, or annual contracts, if cost effective.

Please advise all Medicare contractors of this decision and remind them that they must review HCFA records retention requirements and assure that all records are retained in accordance with these requirements. (See 36 C.F.R. 1228.224.) Contractors should also continue to box and identify the records in accordance with FRCs and HCFA requirements even though the FRCs will no longer accept additional boxes for storage. This will enable the contractors to transfer these records to the FRCs with minimal additional work when the FRCs are reopened for Medicare storage.

If a contractor is unable to locate an offsite storage facility that meets the Federal records retention requirements, then the contractor must submit a written request for temporary relief from these requirements to HCFA's Records Officer. If after one year the facility is still not in compliance or the contractor still cannot locate a storage facility that meets Federal records retention requirements, the contractor must submit a letter to HCFA's Records Officer outlining what actions have been taken and requesting an extension for relief from these standards. Medicare contractors must utilize those available commercial facilities which most closely satisfy Federal records retention standards (taking into consideration the protection of these records from fire, theft and deterioration; avoiding scandal and harm to the Government, and safeguarding personal indicators). The records freeze does not relieve contractors of their obligation to store all records in compliance with the Federal records retention requirements.

Additionally, we wish to advise you we have established a Records Freeze Workgroup to evaluate and prepare recommendations on ways to meet DOJ's concerns regarding record retention. The workgroup is researching various technologies, such as microfilming, CD ROM storage, and optical imaging for maintaining Medicare records in lieu of the hard copy. We will keep you informed of the efforts of this workgroup.

If you have any questions concerning records retention requirements, please contact Vickie Robey at (410) 786-7883. Questions concerning the records freeze, may be directed to Mable Gordon at (410) 786-7507.

Your cooperation is appreciated.

/s/

Vickie Robey
HCFA Records Officer

/s/

Lisa Vriezen
Chief
MSP Operations

cc:
All Regional Administrators
All Associate Regional Administrators for Medicare
All Regional MSP Coordinators
All HCFA Central Office Managers
Records Freeze Workgroup
MSP Staff
All HCFA Centers/Offices

From: Mike Odachowski (HCFA Broadcast)
To: All E-Mail Users
Date: 12/22/99 2:48pm
Subject: HCFA Document Management Responsibilities re Tobacco Litigation

As many of you are aware, the United States has filed suit against the tobacco industry to recover its expenditures for smoking-related medical care and to obtain equity payments under various statutes. HCFA is a major contributor to the Government's case, and our staff is already working closely with the Office of General Counsel (OGC) and the Department to support the Department of Justice (DOJ) litigation team. As a party to the suit, HCFA is subject to various directives from the Federal District Court. I want to make you aware today of such a directive on document management.

On October 19, 1999 Judge Kessler directed:
"Each party shall preserve all documents and other records containing information potentially relevant to the subject matter of this litigation. Each party shall also preserve any physical evidence or potential evidence and shall not conduct any testing that alters the physical evidence without notifying opposing counsel and unless counsel stipulate to the test, without obtaining the Court's permission to conduct the test."

In response to the judge's directive all HCFA components must immediately assure the preservation of tobacco relevant records, including electronic records. No such record may be destroyed or disposed of, even when such actions are part of existing records management retention and disposition processes under the Federal Records Act. Such records include:

1. Documents dealing with smoking-related conditions/diseases or their treatment
2. Grants/payments for research in connection with cigarettes or any aspect of the tobacco industry
3. Nicotine and addiction or youth smoking
4. Payment of benefits for smoking-related conditions
5. Grants/payments for research in connection with cigarettes or the tobacco industry and any documents related to cigarette design including work on developing/marketing potentially safer cigarettes
6. Contacts between officials, employees or agents of HCFA and officials, employees or agents of the tobacco industry, the Council for Tobacco Research or its predecessor, the Tobacco Industry Research Committee, or the Tobacco Institute
7. Any other records which in any way relate to the use of tobacco products

Records which meet the criteria listed above should be catalogued and tracked, so that they may be retrieved, if necessary, to support HCFA's participation in this litigation. It is particularly important that steps be taken to preserve Agency E-mail records regarding tobacco issues. Staff may maintain E-mail records manually by printing the record and keeping the hard copy or electronically by archiving the E-mail records to an archive server on the LAN. Instructions for archiving to an archive server may be found on the HCFANet by clicking on the GroupWise icon and then clicking on Instructions for 180 Day Retention and Archiving. Failure to comply with the document retention and evidence preservation provisions of the court order could subject HCFA employees to monetary and other sanctions.

Questions on tobacco document management issues should be addressed to John Van Walker in the Office of Information Services. John may be reached at 410-786-0951. Where records subject to the directive are inadvertently destroyed, you must notify John immediately and document which records were destroyed and the circumstances which led to their destruction. In addition, 36 CFR 1228.104 requires that the inadvertent destruction of records in agency custody be reported to the National Archives and Records Administration (NARA). Please contact Vickie Robey at 410-786-7883 regarding this provision.

I will notify you when this directive ceases to be in effect. Thank you for your careful consideration of this notice and active support to HCFA in meeting its responsibilities to the Federal District Court.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DATE: August 14, 2003

FROM: Director, Medicare Contractor Management Group
Center for Medicare Management

SUBJECT: Coordination of Responses to Subpoenas and Other Requests from Outside Entities

TO: All Fiscal Intermediaries (FI)
All Carriers

The purpose of this memorandum is to ensure a coordinated and appropriate response to discovery requests involving Medicare drug reimbursement litigation.

On October 3, 2001, the Boston United States Attorney reached a settlement with TAP Pharmaceutical Products, Inc. (TAP) to resolve criminal charges and civil liabilities in connection with its marketing of Lupron®, a prostate cancer drug. Subsequent to the federal settlement, civil suits were filed by Medicare beneficiaries and Medigap insurers against TAP based on the drug pricing scheme at issue in the federal litigation. These cases were consolidated in the District of Massachusetts as In Re: Lupron® Marketing and Sales Practices Litigation. Recently, nationwide subpoenas were issued to Medicare contractors in these cases, seeking extensive discovery related to the subject matter of the false claims act case. Further, we have received information from the Civil Division of the Department of Justice that many more lawsuits, and requests, may follow as a result of the settlement.

The Department of Health and Human Services (HHS), through its counsel, is opposing these requests as not comporting with the Federal Rules of Civil Procedure and our regulations for third-party discovery. The attached document, "lupron-objection.wpd", was directed to party counsels involved in the ongoing civil suits. Because the Centers for Medicare & Medicaid Services (CMS) is not a party to these suits, neither CMS nor the Medicare contractors are under the same obligation to respond as either CMS or its contractors would have been had either been a named party. Contractors should not provide documents in response to these requests unless directed by CMS.

We are concerned that the resources of CMS and the Medicare contractors not be unduly expended in responding to massive discovery in cases in which we are not parties and where the law does not require the government or its contractors to respond. Where responses may be required, we must ensure that any responses be coordinated with counsel for CMS.

Therefore, we request that all FIs and Carriers refrain from responding to any subpoenas concerning TAP, Lupron®, Zoladex®, drug companies other than TAP, or any other drug reimbursed by Medicare unless directed to do so by Regional Counsel for HHS. We also request that you send a copy of any subpoena received to the appropriate Regional Counsel contact. The Regional Chief Counsels have designated the following counsel as contacts for this matter:

Region I	Clifford Pierce	(617) 565-2379
Region II	Rachel Park	(202) 264-1174
Region III	Michael Leonard	(215) 861-4455
Region IV	Sherman Johnson	(404) 562-7815
Region V	Sheila Hegy	(312) 886-1701
Region VI	Christopher Maxwell	(214) 767-3487
Region VII	Duane Bruce	(816) 426-6513 x229
Region VIII	Patricia Bossert	(303) 844-7806
Region IX	Joseph Stein	(415) 437-8167
Region X	Aaron Brown	(206) 615-2525

If you have provided any information regarding any request concerning the aforementioned matter, you should immediately notify the appropriate Regional Counsel contact.

Thank you for your attention to this matter. If you have further questions regarding this letter, please contact Verne Rinker of my staff at (410) 786-8867 or vrinker@cms.hhs.gov.

/s/
Gregory G. Carson

Attachment

cc:
All RAs
All CCMOs
Lou Polise, CMM/MCMG
Verne Rinker, CMM/MCMG
Carole Kagan, OGC

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850
JSM-15, 11-18-03

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DATE: November 18, 2003

FROM: Director, Medicare Contractor Management Group
Center for Medicare Management

SUBJECT: Coordination of Responses to Subpoenas and Other Requests from Outside Entities Regarding TAP Pharmaceutical Products, Inc. and Lupron® – Part II
-Preservation of Documents and Contact Identification

TO: All Fiscal Intermediaries (FI)
All Carriers
All Durable Medical Equipment Regional Carriers

This memorandum follows on the August 14, 2003, memorandum entitled "Coordination of Responses to Subpoenas and Other Requests from Outside Entities," which related to the October 3, 2001, settlement that the Boston United States Attorney reached with TAP Pharmaceutical Products, Inc. (TAP) to resolve criminal charges and civil liabilities in connection with its marketing of Lupron®, a prostate cancer drug. The prior communication requested that you refrain from responding to requests for information related to certain drug companies or drugs reimbursed by Medicare unless directed to do so by the Department of Health and Human Services (HHS) Regional Counsel.

In order to preserve the government's interest, the Department of Justice and the HHS Office of the General Counsel (OGC) have requested that documents related to Medicare drug reimbursement be preserved. You should identify, retain and not destroy any documents, in whatever form maintained, that are encompassed by the subject matter of the August 14, 2003, memorandum: i.e., any documents that concern TAP, Lupron®, Zoladex®, drug companies other than TAP, or any other drug reimbursed by Medicare.

Further, you should identify a single contact person within your organization to receive future correspondence relating to this matter and to coordinate future activities. Please forward the name, telephone number, address and e-mail address of this individual within 10 business days of receipt of this memorandum to Troy Barsky of HHS OGC, the Centers for Medicare & Medicaid Services (CMS) Division, at (202) 205-8689 or troy.barsky@hhs.gov.

As a reminder, you should notify your HHS Regional Counsel contact if you receive any request for information related to this matter. The Regional Chief Counsels have designated the following counsel as contacts for this matter (Please note, these are the same contacts as were identified in the October 14, 2003, memorandum):

Region I	Clifford Pierce	(617) 565-2379
Region II	Rachel Park	(202) 264-1174
Region III	Michael Leonard	(215) 861-4455
Region IV	Sherman Johnson	(404) 562-7815
Region V	Sheila Hegy	(312) 886-1701
Region VI	Christopher Maxwell	(214) 767-3487
Region VII	Duane Bruce	(816) 426-6513 x229
Region VIII	Patricia Bossert	(303) 844-7806
Region IX	Joseph Stein	(415) 437-8167
Region X	Aaron Brown	(206) 615-2525

Thank you for your attention to this matter. If you have further questions, please contact Verne Rinker of my staff at (410) 786-8867 or vrinker@cms.hhs.gov. Please keep Mr. Rinker informed of your activities in response to these requests.

/s/
Gregory G. Carson

cc:
All RAs
All CCMOs
Lou Polise, CMM/MCMG
Jeff Hinson, CMM/MCMG
Verne Rinker, CMM/MCMG
Vickie Robey, OOM
Carol Bennett, OGC
Carole Kagan, OGC
Troy Barsky, OGC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs

200 Independence Avenue SW
Washington, DC 20201

PRIVILEDGED AND CONFIDENTIAL

DATE: FEB 19 2004

TO: All Center and Office Directors
Regional Administrators

FROM: Jacquelyn Y. White
Director
Office of Strategic Operations and Regulatory Affairs

SUBJECT: Document Preservation and Production - Lupron Marketing and Sales Practices Litigation, and Pharmaceutical Industry Average Wholesale Price Litigation

REPLY DUE BY: February 25 and March 12, 2004

On October 23, 2003, and December 18, 2003, the Department of Health and Human Services (HHS) was served with two virtually identical subpoenas requesting documents and other responsive information related to the above-referenced litigation. The purpose of this memorandum is to provide guidance to ensure that the CMS Central Office and all CMS Regional Offices identify and provide to the Office of General Counsel (OGC), information necessary to respond to the attached discovery requests.

Please be aware that this memorandum is privileged and confidential, and should not be disclosed outside your office without prior OGC approval.

BACKGROUND

Both of the cases identified in the subject line above actually consist of several separate lawsuits from around the country which have been consolidated into two multi-district actions (MDLs) in the United States District Court for the District of Massachusetts. The two MDL cases are commonly referred to as the Lupron MDL and the AWP Litigation MDL. In both, numerous private and state government plaintiffs have alleged that the defendant drug manufacturers inflated the "average wholesale price" (AWP) for their drugs which they reported to pharmaceutical pricing compendia. The inflated AWP far exceeded the actual acquisition costs paid by physicians for those drugs, according to these allegations. As a result, Medicare, which reimbursed physicians for these drugs based upon the reported AWP, paid inflated amounts. (Plaintiffs are either Medicare beneficiaries who seek return of the inflated portion of their co-pay or state governments that are bringing consumer protection claims on behalf of their citizens.) The plaintiffs in the Lupron MDL make

these allegations against defendant TAP Pharmaceuticals as to its drug Lupron.[1] The plaintiffs in the AWP Litigation MDL make these allegations against various other drug manufacturers in connection with other Medicare-covered drugs.

The defendants contend that they are not liable because the Federal Government, including CMS, was aware that drug AWPs, reported to pricing compendia did not accurately reflect actual acquisition costs. The defendants have served the attached subpoenas on HHS in order to search for records that establish this point.

The United States is not a party to any of these lawsuits. Nonetheless, the Federal Rules of Civil Procedure, which govern these cases, impose certain obligations upon CMS as a non-party with potentially relevant information to the claims and defenses in these cases.

REDACTED MATERIAL

[1] In 2001, TAP Pharmaceuticals paid approximately $850 million to the United States in settlement of civil and criminal claims arising from these allegations.

PRIVILEDGED AND CONFIDENTIAL

Promptly designate a person who will coordinate your discovery responses. Please e-mail your designee's name and telephone number to Glenda Bailey of my staff at GBailey1@cms.gov and Troy Barsky of OGC at Troy.Barsky@hhs.gov by **February 25, 2004**. All responsive documents must be delivered to OGC by **March 12, 2004**. Upon delivery to OGC, please notify Glenda that you have complied with this request.

If you have any questions or need additional information, please call Glenda at (410) 786-6538 or Troy Barsky at (202) 205-8689.

Attachments